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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,697	04/05/2002	Akane Takemura	011633	3246

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EXAMINER	
PORTER, RACHEL L	
ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/926,697	TAKEMURA ET AL.	
	Examiner	Art Unit	
	RACHEL L. PORTER	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/29/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-47,51 and 52* is/are pending in the application.

4a) Of the above claim(s) *23-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47, and 51-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 12/29/08. Claims 23-47, 51-52 are pending. Claims 23-46 have been withdrawn from consideration. Claims 47 and ,51-52 are presented for examination.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 47 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

In the instant case, the preamble of claim 47 recites a sheet. Furthermore, the body recites “a risk avoidance measure presentation processing part” and "a risk estimation processing part” with a plurality of other parts. In other words, the current invention appears to be a compilation of data.

Applicant has argued that the recited sheet is a paper medium and is therefore an article of manufacture. However, it is noted a mere arrangement of printed matter, though seemingly a “manufacture,” is rejected as not being within the statutory classes.

See *In re Miller*, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967). (See MPEP 706.03(a))

Furthermore, the descriptions of the data on the various parts of the sheet are non-functional descriptive material. It should be noted that non-functional descriptive material even when recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e., abstract ideas, stored on a computer-readable medium, in a computer, or on an electromagnetic carrier signal, does not make it statutory. See *Diamond v. Diehr*, 450 U.S. 175,185-86, 209 USPQ 1. (See MPEP 2106.01)

[Claim 51]

Claim 51 is dependent from claim 47, and fails to correct the deficiencies of claim 47. In particular, claim 51 recites a risk care set comprising the sheet of claim 47 and guidance tools comprising any one of: videos, CDs, cassette tapes, panels, books, computer software.

Certain types of descriptive material, such as music, literature, art, photographs, and mere arrangements or compilations of facts or data, without any functional interrelationship is not a process, machine, manufacture, or composition of matter. As explained in the rejection of claim 47, a mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See *In*

re Miller, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967). (See MPEP 706.03(a)). Therefore, the recited "videos, CDs, cassette tapes, panels, books" with the recited content are considered non-statutory.

As to the recitation of "computer software, data structures not embodied on a computer-readable medium are considered descriptive material. They are therefore considered non-statutory because they are not capable of causing a functional change in a computer. As drafted, the claim fails to define any structural and functional interrelationships between the code and other elements of a computer that permit the computer program's functionality to be realized.

In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory. (See MPEP § 2106.01)

The current language of claim 51 fails to recite statutory subject matter and also fails to correct the issues of claim 47. Therefore claim 51 is rejected under 35 USC 101.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 47, and 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. .

In particular, claim 47 recites a "risk improvement sheet," but it is unclear which form the recited sheet takes. In other words, as described in the on page 18, lines 8-21 of the specification, the risk improvement table is described in a plurality of embodiments. These include a paper medium, or table display realized using a computer program. At present, the claim language recites " a risk estimation *processing* part" and "a risk avoidance measure presentation *processing* part." However, if applicants intends to claim merely a sheet (e.g. a paper medium), as argued in on page 11 of the response filed 12/29/08, it is unclear how portions of a page or any display item alone can function in a "processing" capacity. It is noted that the claim has been amended. However, the claim amendment fails to clarify the claim issues.

For the purpose of applying art, the examiner will interpret the claim language and the recited sheet to be any printed medium.

Claims 51 and 52 inherit the deficiencies of claim 47 through dependency and are therefore also rejected.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Dewey et al (US 5,084,819).

[claim 47] Dewey discloses a disease risk improvement sheet comprising a risk estimation processing part and a risk avoidance measure presentation processing part, wherein said risk estimation processing part has:

- a data gathering part provided with an examination item display section that displays a plurality of risk factors and means for examining the presence or absence or current state of the risk factors, and an answers section corresponding to the examination item display section; (Figure 3 (answers) ; Tables 1,5—solicits users for questions and answers are shown)
- a judgment criteria part provided with a risk value judgment criteria section that stipulates an unequivocal correlation between the answers and preset risk values; (Tables 5- assigns weights to answers and determines a score; (see also table 4 which includes criteria))
- a risk judgment part provided with a judgment section for recording the risk values for the risk factors converted from the answers of the answers section based on the risk value judgment criteria section and calculating an overall risk value by arithmetic processing; and (Tables 1,5 (see also table 4 which includes criteria))
- an overall risk display part provided with an overall risk judgment criteria section that unequivocally stipulates an overall risk allocated to one of a plurality of preset levels

from the overall risk value, the overall risk display section that displays an overall risk showing a risk level of an examinee, and an explanation section that explains the risk level and, (Table 5 –summarizes weighted answers, gives risks and scores)

- wherein said risk avoidance measure presentation processing part has
    - a risk avoidance measure display part provided with a risk avoidance measure criteria section in which are shown the necessity of re-examination ad the time of re-examination (recall judgment) (Tables 5; col. 7, lines 64-col. 8, line 10) , a guidance display section in which are displayed guidance contents for guiding lifestyle so as to reduce the risk, (Table 5) and a means display section in which are display tools for carrying out the risk improvement in accordance with a guidance of said display section; and (Table 5)
    - an improvement possibility display part. (Table 5)

Regarding the description of the risk improvement sheet as an “oral disease” risk improvement sheet , a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Furthermore, It should also be noted that the details regarding the contents and parts of the “oral disease” risk improvement sheet are non-functional descriptive material. However, these limitations are nonfunctional description material and are not functionally involved or required for table. Thus, this descriptive material will not

distinguish the claimed invention from the prior art in terms of patentability. See *In re Gulack,* 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry,* 32F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dewey in view of Connelly (US 5,738,113)

[Claim 51] Dewey discloses an oral disease risk improvement sheet recited in claim 47 as explained in the rejection of claim 47.

Dewey does not expressly disclose providing a risk improvement tools including guidance tools comprising any one of videos, CDs, cassette tapes, panels, books, computer software containing guidance on improving eating habits and brushing guidance used for the purpose of teaching knowledge and increasing awareness with regard to oral hygiene, diseases, or products for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators.

Connelly discloses providing risk improvement tools to patients including products (e.g. panels-home instructions) for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators. (Col. 9, lines 55-65; col. 10, lines 1-60, Table 4; e.g. panels-home instruction kits). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Dewey with the teaching of Connelly to include panels/products to prevent or reduce disease risk. As suggested by Connelly, one would have been motivated to include these features to provide cost-effective, inexpensive interventions which require minimal dental infrastructure (col. 2, lines 25-29)

[Claim 52] Dewey discloses an oral disease risk improvement sheet recited in claim 47 as explained in the rejection of claim 47.

- examination means for implementing a question-based examination and an oral cavity examination as indicated by said risk improvement table on each test subject; (Figure 3, Table 1—"as indicated by said risk improvement table" is question and answer inventory)
- calculating means for applying examination results to the "risk estimation" processing part of said risk improvement table, working out a risk value for each risk factor judged objectively, and calculating an overall risk value; and (Tables 4-5)

Dewey does not expressly disclose providing a risk improvement tools including guidance tools comprising any one of videos, CDs, cassette tapes, panels, books, computer software containing guidance on improving eating habits and brushing guidance used for the purpose of teaching knowledge and increasing awareness with regard to oral hygiene, diseases, or products for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators.

Connelly discloses providing risk improvement tools to patients including products (e.g. panels-home instructions) for the oral cavity comprising any one of the mouthwashes, sprays, foams, gels, tablets, chews, capsules, gum, foods, toothbrushes, interdental brushes, dental floss, and irrigators. (Col. 9, lines 55-65; col. 10, lines 1-60, Table 4; e.g. panels-home instruction kits). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Dewey with the teaching of Connelly to include panels/products to prevent or reduce disease risk. As suggested by Connelly, one would have been motivated to include these features to provide cost-effective, inexpensive interventions which require minimal dental infrastructure (col. 2, lines 25-29)

Response to Arguments

9. Applicant's arguments filed 12/29/09 have been fully considered but they are not persuasive.

(A) Applicant argues that Dewey does not disclose all of the limitations of Claim 47, including the newly added limitations.

In response, the Examiner has provided additional citations and expanded on the rejections to clarify the Examiner's positions. However, it is noted that claim 47 on the whole is directed to non-statutory subject matter. (i.e. the current invention appears to be a compilation of data)

Applicant has argued that the recited sheet is a paper medium and is therefore an article of manufacture. However, it is noted a mere arrangement of printed matter, though seemingly a "manufacture," is rejected as not being within the statutory classes. See *In re Miller*, 418 F.2d 1392, 164 USPQ 46 (CCPA 1969); *Ex parte Gwinn*, 112 USPQ 439 (Bd. App. 1955); and *In re Jones*, 373 F.2d 1007, 153 USPQ 77 (CCPA 1967). (See MPEP 706.03(a))

Furthermore, the description of the data on the various parts of the sheet are non-functional descriptive material. Again, non-functional descriptive material even recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e., abstract ideas, stored on a computer-readable medium, in a computer, or on an electromagnetic carrier signal, does not make it statutory. See *Diamond v. Diehr*, 450 U.S. 175,185-86, 209 USPQ 1. (See MPEP 2106.01)

(B) Applicant argues that none of the references discloses "Applicant's objects" of determining the oral health of a single person, good oral hygiene habits, and general health awareness.

In response, the prior art In response to applicant's argument that the applicant's objects have not been disclosed by the prior art, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Gillio (US 5,755,577); Simone (US 7,319,970); Hayward et al (5,574,828).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL L. PORTER whose telephone number is (571)272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, (Christopher) Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. L. P./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626